UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	
	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All cases	)	

Amended Notice of 30(b)(6) Deposition of the Massachusetts Board of Registration in Pharmacy

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Federal Rule of Civil Procedure 30(b)(6), come now and amend the notice that the oral and videotaped deposition of the Massachusetts Board of Registration in Pharmacy ("Mass. BoP"), as an organization, will be taken on the topics detailed below.[1] The Mass. BoP shall identify the person(s) who will speak on its behalf on each topic at least seven (7) days before the deposition(s).

The deposition will take place at World Trade Center, 200 Seaport Boulevard, Federal Complex Room (Mezzanine Level), Boston, MA 02210. The deposition will be

[1] This amended notice adds numbered topic 10 regarding approval of the NECC prescription order form.

recorded by stenographical means and by video. The deposition will begin on December 4, 2015, at 9:00 am EST.

Pursuant to Federal Rule of Civil Procedure 30(b)(6), the Mass. BoP's designee(s) shall be prepared to testify regarding the following subjects:

Mass. BoP's authority to investigate, inspect, regulate, and take action against NECC

1. The Mass. BoP's authority under Massachusetts law to investigate, inspect, regulate, and take enforcement action against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") during the time of NECC's operation.

2. The Mass. BoP's internal policies (written or otherwise), procedures (written or otherwise), and training of staff from 2002 to the time of the meningitis outbreak on the (1) inspection of compounding pharmacies, (2) when regulatory action was appropriate against compounding pharmacies, and (3) distinguishing between traditional pharmacies, traditional compounding, large-scale compounding similar to drug manufacturing (now called "outsourcing facilities"), and conventional drug manufacturers.

3. Generally, the Mass. BoP's authority to take enforcement actions against pharmacies, and how that authority can be exercised (*i.e.*, generally, the differences between the types of enforcement actions available to the Mass. BoP, *e.g.*, private censures, warning letters, seizures, injunctions, criminal actions, civil penalties, *etc.*).

Mass. BoP's investigation, inspections, regulation, and actions related to NECC

4. NECC's 1998 Application for Registration to Manage and Operate a New Community Pharmacy.

5. All complaints about NECC known by the Mass. BoP prior to the meningitis outbreak and the Mass. BoP's response to these complaints, including the internal decision-making regarding whether and how to investigate, inspect, and take action against NECC. The complaints and related investigations, inspections, and actions that the witness should be prepared to testify about include, but are not limited to:

a. 1999 private, non-disciplinary letter to NECC regarding providing blank prescription forms to physicians;

b. Complaint from the Idaho Board of Pharmacy to Mass. BoP in 2001 notifying the Mass. BoP that NECC continued to use blank prescription forms;

c. Complaints about NECC that the Mass. BoP received from the Nevada Board of Pharmacy in April 2002;

d. The joint investigations of NECC conducted by the Mass. BoP and the FDA in April 2002 and from October 2002-February 2003, and the results of the investigations;

e. The formal complaint filed by the Mass. BoP against NECC in February 2003;

f. The meeting in February 2003 between the FDA and Mass. BoP and the plan of action developed regarding addressing the ongoing issues with NECC;

g. February 2004 and September 2004 inspections of NECC by the Mass. BoP and the FDA;

h. The three private censures of NECC in 2004 by the Mass. BoP;

i. The 2006 Consent Agreement between NECC and the Mass. BoP;

j. The 2006 assessment reports by Pharmacy Support, Inc. required by the 2006 Consent Agreement with NECC;

k. The warning letter sent to NECC in 2006 by the FDA arising from the 2004 joint inspection by the FDA and Mass. BoP;

l. The indication in the 2006 Warning Letter that NECC was not using patient-specific prescriptions for compounded medications;

m. The 2011 and 2012 reports from the Colorado Board of Pharmacy to the Mass. BoP regarding NECC's actions in Colorado and the Mass. BoP's actions (or lack of action) against NECC based on these reports; and

n. The inspection of NECC by the Mass. BoP on May 24, 2011.

6. Any and all complaints about NECC received by the Mass. BoP or actions by the Mass. BoP in response to complaints about NECC not specifically referenced in Number 5(a)-(n).

7. Any and all correspondence and communications between the Mass. BoP and NECC (including its owners, agents, employees, and representatives) not specifically referenced in Number 5(a)-(n).

8. Any and all correspondence and communications between the Mass. BoP and the FDA or other state pharmacy boards related to NECC not referenced in Number 5(a)-(n).

NECC's prescription order form

9. Any and all correspondence and communications between the Mass. BoP and NECC related to the review and/or approval of NECC's prescription order form.[2]

Cooperation with the FDA

10. Whether, based on information learned by the Mass. BoP about NECC prior to the meningitis outbreak, the Mass. BoP believed that NECC was operating like a conventional drug manufacturer (or, at a minimum, operating on a scale not akin to a traditional pharmacy compounder), subjecting it to FDA regulatory authority, or whether

[2] *See* Deposition of Linda Pino at pages 149:2-16 and 163:9-20, attached as **Exhibit 2**.

the Mass. BoP believed NECC remained within the regulatory authority of the Mass. BoP.

11. Information about NECC that the FDA shared with the Mass. BoP prior to the meningitis outbreak and any enforcement action the FDA suggested the Mass. BoP should take against NECC's state license.

12. The Mass. BoP's cooperation with the FDA in investigating, inspecting, and taking action against NECC prior to the meningitis outbreak.

13. The Mass. BoP's public statements since the outbreak regarding (1) whether it should have but failed to take disciplinary actions against NECC at the junctures described in 5(a)-(n) above (or at any other times); (2) whether these failures constituted a negligent failure to exercise its regulatory duty; and (3) whether these failures caused or contributed to the meningitis outbreak.

The information known by the Mass. BoP about NECC and whether/how it was made public

14. What, if any, of the information known by the Mass. BoP about NECC's failure to follow federal law, state law, or industry standards for production of drugs was made publicly available prior to the meningitis outbreak and the steps necessary for potential customers of NECC to obtain the information from the Mass. BoP.

15. What information about NECC the Mass. BoP would have provided to someone requesting information about NECC in 2011 or 2012 prior to the meningitis outbreak.

16. Whether the Mass. BoP issued any alerts to health care providers or other government agencies prior to the meningitis outbreaks related to NECC (*e.g.*, that it was

unsafe to purchase from NECC; that it was unsafe to purchase certain drugs from NECC; that NECC was operating in violation of federal or state law; *etc.*).

Mass. BoP's investigation and inspection of, and action against NECC, following the meningitis outbreak

17. The findings of the Mass. BoP based on its investigation and inspection of NECC following the meningitis outbreak as captured in its October 23, 2012, report, including (but not limited to):

a. The Mass. BoP's finding that NECC distributed recalled lots of MPA before it received sterility testing results;

b. Observation of visible particulate matter in several recalled sealed vials of MPA from Lot 08102012@51;

c. NECC's failure to follow proper USP 797 autoclaving sterilization procedure;

d. NECC's cleanrooms used to compound drugs were not appropriately sealed;

e. NECC's cleanrooms used to compound drugs were not thoroughly cleaned pursuant to USP 797 or NECC's standard operating procedures; and,

f. Whether NECC failed to comply with other USP standards.

Ameridose and Alaunus Pharmaceuticals

18. The findings of the Mass. BoP's inspections and investigations of Ameridose and Alaunus Pharmaceuticals ("sister" companies owned and operated by the same owners and operators of NECC), including, but not limited to:

a. Whether the Mass. BoP had knowledge of 2009 complaints from Ameridose employee(s) that the owners and operators of Ameridose (the same owners and operators as NECC) directed outside testing companies to change results, forged documents, and "doctored" findings;

b. Whether the Mass. BoP had knowledge of July 2010 complaints by a pharmacist at Ameridose that Ameridose was ignoring its quality assurance program;

c. Whether the Mass. BoP had knowledge of August 2010 complaints by a pharmacist at Ameridose that Ameridose had its sales team labeling drugs in a clean room, that a clean room had tested positive for mold growth, and that Ameridose was manipulating its environmental testing;

d. Whether the Mass. BoP had knowledge of February 2011 complaints about Ameridose not safely labeling its compounded sodium chloride;

e. Whether the Mass. BoP had knowledge of August 2011 complaints by an Ameridose employee that Ameridose's management instructed its staff to ship packages even if they were dropped on the floor in a dirty room; and

f. Whether the Mass. BoP had knowledge at any time of complaints or allegations that Ameridose was compounding or manufacturing drugs for NECC because NECC did not have the capacity to fill large orders.

Documents

19. The documents that the witness(es) is requested to produce in the *duces tecum* attached as **Exhibit 1** to this Notice.

Respectfully submitted this November 23, 2015.

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
315 Deaderick Street, Suite 1100
Nashville, TN 37238
Ph: (615) 254-0400
Fax: (615) 254-0459
chris@gideoncooper.com
Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 23rd day of November, 2015. The amended notice is also being served on counsel of record for the Massachusetts Board of Registration in Pharmacy via email.

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT 1

***Duces Tecum* to Notice**

EXHIBIT 1 – *DUCES TECUM*

Instructions: To the extent these documents can be provided electronically by posting to a web-based repository or provided on CD or flash drive, that would be preferable.

1. The witness's most current professional resume or *curriculum vitae.*

2. Any and all *public* documents related to NECC (documents the Mass. BoP made available to the general public) in the possession or control of Mass. BoP *prior to the meningitis outbreak*.

3. Any and all *non-public* documents related to NECC (documents the Mass. BoP did *not* make available to the general public) in the possession or control of Mass. BoP *prior to the meningitis outbreak*.

4. Any and all documents related to NECC in the possession or control of the Mass. BoP since the meningitis outbreak.

   Further instructions on requests 2, 3, and 4:

   Requests 2 and 3 seek production of the pre-outbreak Mass. BoP "file" for NECC available to the public (request 2) and separate production of the pre-outbreak internal Mass. BoP "file" for NECC not available to the general public (request 3). Request 4 ensures that all NECC-related documents, including those related to the outbreak through the present, are produced.

   To the extent these documents have, since the outbreak, been posted on a website for public access, please identify the specific website where the Tennessee Clinic Defendants can access the entirety of the documents and determine what was publicly available prior to the outbreak versus what was part of the Mass. BoP's non-public file.

   If some documents are withheld on assertion of privilege or for any other reason, please identify the documents with reasonable particularity and the reason the documents have been withheld.

5. All treatises, scholarly journals, professional studies, professional literature, or similar documents the witness intends to rely upon in giving testimony responsive to this Notice.

6. Any and all documents, not privileged, reviewed or relied on by the witness in preparation for giving testimony pursuant to the Notice.

7. Mass. BoP's internal policies, procedures, or training materials in place from 2002 to the time of the meningitis outbreak related to the investigation, inspection, and regulation of, and enforcement action against, (1) compounding pharmacies, generally, and (2) large-scale compounding pharmacies (compounding pharmacies operating beyond the definition of traditional compounding and acting more similar to conventional drug manufacturers).

8. Any documents provided by NECC to the Mass. BoP at any time as part of the Mass. BoP's investigations of NECC.

9. Any documents provided by the FDA to the Mass. BoP related to investigations of NECC.

EXHIBIT 2

VOLUME: I
PAGES: 1-187
EXHIBITS: 72-101

VIRGINIA

IN THE CIRCUIT COURT FOR THE
CITY OF ROANOKE No. CL12-2547

****
SHARON G. WINGATE, EXECUTOR of*
the ESTATE OF DOUGLAS GRAY *
WINGATE, DECEASED, *
Plaintiff *
VS. *
INSIGHT HEALTH CORP., JOHN *
MATHIS, M.D., ROBERT F. *
O'BRIEN, M.D. *
AND *
IMAGE GUIDED PAIN MANAGEMENT, *
P.C., *
Defendants *
****

DEPOSITION of LINDA DIANE PINO, a witness called on behalf of the Defendant, Insight Health Corp., taken pursuant to the applicable provisions of the Virginia Rules of Civil Procedure, before Jane M. Walsh, Shorthand Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the offices of Bonner, Kiernan, Trebach & Crociata, 200 Portland Street, Boston, Massachusetts, on Tuesday, November 12, 2013, commencing at 10:45 a.m.

A Okay.
Q I think it's right on the top. This has a prescription order form on it; doesn't it?
A Yep.
Q If you could turn to that Page 6169 on Exhibit 72.
A This one? (Indicating)
Q Yes, Ma'am.
A Okay.
Q All right. This one is for sure the prescription order form that you first gave to the pain clinic in Roanoke, Virginia; is that right?
A Right, and the thing was on this, I mean, they fine tuned this. This was approved by the Pharmacy Board.
Q And this was to be filled out for any order of drugs; is that correct?
A With the exception of pain pumps.
Q The pain pumps had one more step required?
A They had to send in an individual prescription.
Q Individual prescription?
A And they didn't do multiples on the pain pumps. It was one pump per person.

process. So he was very proud of the medication he put out and the sterility and safeguards he had in place.

Q You mentioned a consultant that was brought in at some point. I'm going to give you a name, see if it rings a bell. Did you ever hear of Pharmacy Support, Inc.?

A No.

Q Okay. Were you ever told at any time while you were there that New England Compounding had had to enter into consent decrees with the Massachusetts Board of Pharmacy?

A What?

Q Consent decrees where they say we agree to do these corrective measures and that sort of thing?

A No. All I remember was the order form had to be a certain way according to the Pharmacy Board of Massachusetts. I think they tightened it up.

Q Were you all ever informed while you were there that patients had developed bacterial meningitis symptoms from any of the ESI injections?